

A New Asia-Pacific Collaboration 「MASTER KEY ASIA」 : Promoting genomic medicine throughout Asia



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National Cancer Center, Japan

Summary

- “MASTER KEY Asia” has launched, a prospective international registration study for rare cancers with ten partner facilities within the Asia-Pacific including Malaysia, Thailand, Indonesia, Philippines, and Vietnam.
- The first academic participants are from Malaysia and the Philippines, with whom processes such as external quality assurance of patients’ samples are shared, with a central pathological review, and genomic analysis conducted in Japan.
- By accumulating data to the largest rare cancer database worldwide, MASTER KEY Asia will accelerate clinical development and genomic medicine throughout Asia. Genomic information, treatment details and prognosis of rare cancer patients will be aggregated to promote international multicenter clinical trials.

The “MASTER KEY Asia Project,” an international collaboration promoting rare cancers research and development throughout Asia including Malaysia, Thailand, Indonesia, Philippines, and Vietnam, led by the Hospital (NCCH; director: Kazuaki SHIMADA) of the National Cancer Center (president: Hitoshi NAKAGAMA) is launched.

This project builds onto the “MASTER KEY Project (Japan)” launched in 2017, for driving research and development for rare cancers and for promoting genomic medicine, a successful collaboration between industry and academia. It has already enrolled over 2000 patients in Japan. We have now opened this registry to Asian partners. Genomic information, treatment details, and prognoses will be aggregated to a large-scale database, comprising the registry arm. It also has an arm for conducting investigator/industry initiated trials with rare cancer patients.

Genomic medicine for cancer patients is not yet common in Asia. With this project, genomic information from Next Generation Sequencing (NGS), together with treatment details, and prognoses will be collected. MASTER KEY Project (Japan) had 2107 patients registered as of September 2021, the largest database worldwide for rare cancers. 12

pharmaceutical companies have joined in the study, 19 clinical trials have been conducted (12 investigator-initiated, 7 pharmaceutical-sponsored). With the expansion, enrollment of 1000 patients per year from Asia including Japan are anticipated.

Collaborating with Asian countries, with which more genomic characteristics are shared as opposed to western countries, and leveling up of cancer genomic medicine in the region is indispensable to driving discoveries for Asian patients and to deliver Asian-specific effective treatments to rare cancer patients.

Having developed the gene panel test “OncoGuide™ NCC Oncopanel System” through the "TOP-GEAR project" and followed through with its implementation with advanced medical care, and establishing a center dedicated to rare cancers, NCCH has launched a project for establishing a clinical trials network for Asia, ATLAS project in 2020. MASTER KEY Asia will work in sync with ATLAS on developing new drugs for rare cancers.

Background

Rare cancers are defined as "malignant tumors with an incidence of less than 6 per 100,000 people per year". Rare cancers comprise nearly 200 cancer types for example, soft tissue sarcoma, GIST, pediatric cancers, brain tumors, eye tumors, skin cancer, head and neck cancers, malignant mesothelioma, cancer of unknown primary, neuroendocrine tumors and hematological cancers. Due to its rarity, standard treatments are yet to be established unlike common cancers, and the prognoses remain poorer than for common cancers.

Rare cancers altogether account for about 22% of all cancer patients. With half of cancer patients worldwide anticipated from Asia, there is a pressing need to invite Asian countries to participate in clinical trials for developing treatments for rare cancers. With smoking rates remaining high, implementation of cancer screening and genomic medicine still in initial stages, we wish to support building the infrastructure for clinical research and clinical trials throughout Asia.

MASTER KEY Asia

“Personalized medicine” is introduced with testing of genomic alterations, guiding molecular targeting therapies. However, these studies with NGS analysis focus on common cancers, limiting studies of rare cancers. Moreover, most clinical trials are based in Europe or the US, there is limited biological information focusing on Asian populations.

The "MASTER KEY Project" targets progressed rare cancer, cancer of unknown primary and rare subtypes of common cancers, consisting of two major arms. The first is a registry study that comprehensively collects genetic and clinical information, prognostic data, etc. of patients with rare cancers and constructs a large-scale database (registry part). The

second comprises new generation clinical trials called “basket trials” (sub-study part) based on specific biomarker tests. Launched in 2017 by NCCH, four partner institutions have joined the scheme, recording a larger number of patient registrations than hoped for.

With “MASTER KEY Asia,” clinical information of ever more rare cancers will become available, accelerating research of target variants and treatment development.

We will work in sync with the Asian clinical Trials network for cAncerS project: ATLAS project, to establish a clinical trial infrastructure in Asia whilst advancing clinical research, preparing to tackle the exponential growth in Asia.

MASTER KEY Project

July, 31st 2017 press release

https://www.ncc.go.jp/jp/information/pr_release/2017/0731/index.html

MASTER KEY project

<https://www.ncc.go.jp/jp/ncch/masterkeyproject/index.html>

MASTER KEY Asia

PI

Noboru YAMAMOTO

Participating Sites

Malaysia

- Sarawak General Hospital
- Hospital Sultan Ismail
- Hospital Kuala Lumpur
- National Cancer Institute
- Hospital Pulau Pinang
- University Malaya Medical Center

Thailand

- Ramathibodi Hospital

Indonesia

- Dharmais Hospital

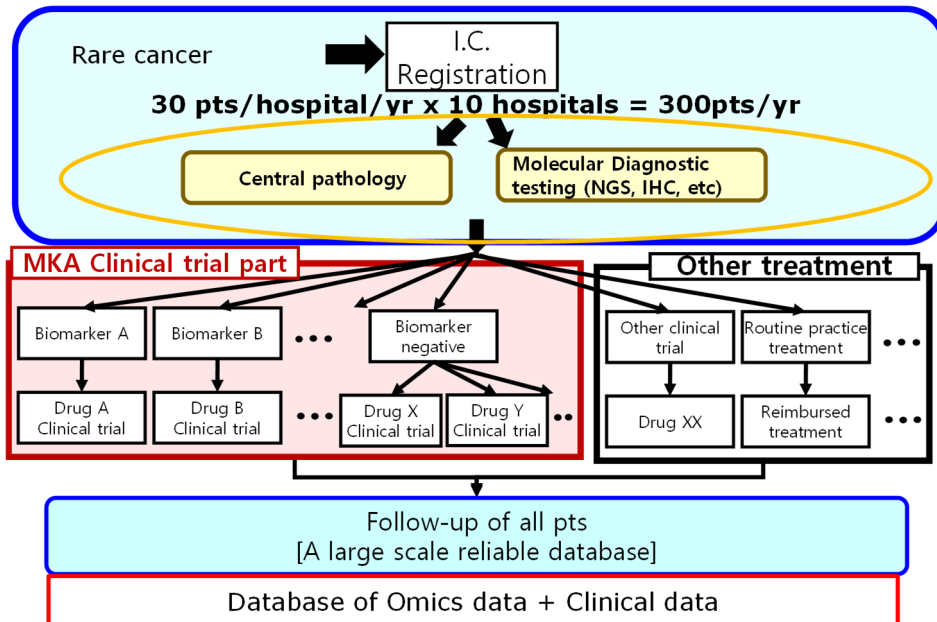
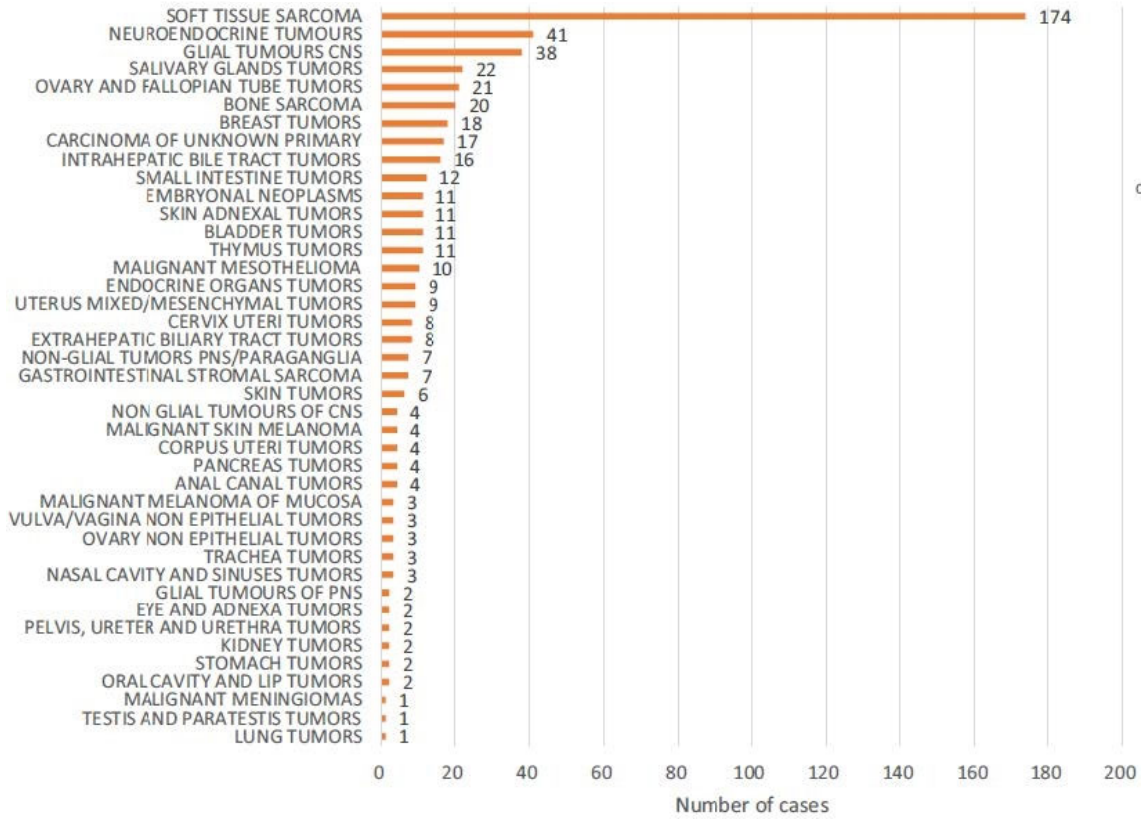
Philippines

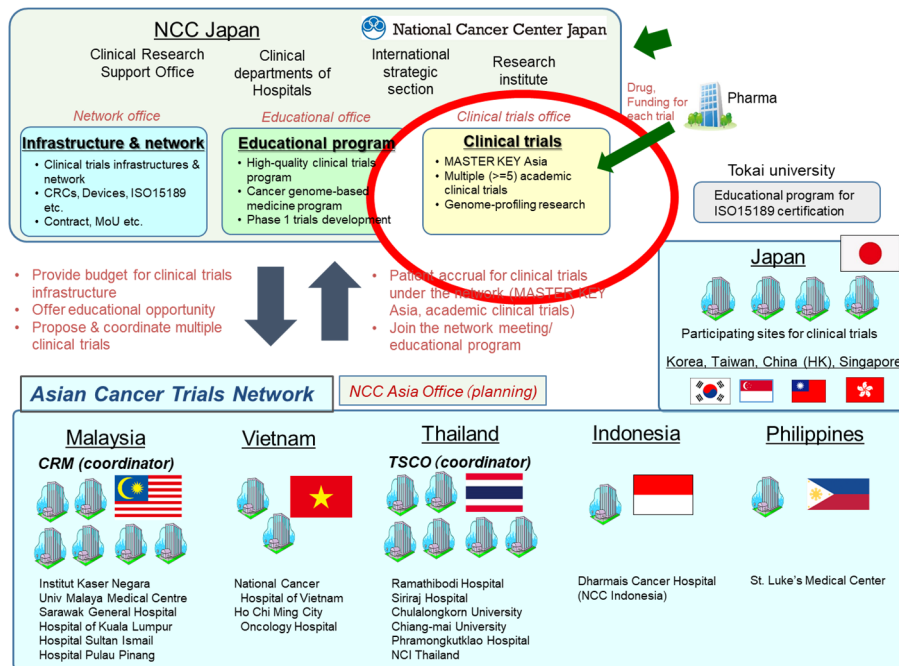
- St Luke's Medical Center

Vietnam

- Ho Chi Minh City Oncology Hospital
- National Cancer Institute

Figure1 Cancer types included in MASTER KEY





「ATLAS Project」

The ATLAS project aims to build an Asian cancer clinical trials network with medical institutions where multiple registration-directed trials can be conducted on a constant basis, by means of reinforcing international collaborative research operations at NCCH and developing clinical trial infrastructure at ASEAN countries. The project is mainly for investigator-initiated registration-directed trials, but investigator-initiated non-registration trials and industry-sponsored trials can also utilize this platform. Improving cancer patients' drug access and implementing genomic medicine is our mission, solving Asia specific issues by Asians. The initiative is anticipated to benefit the entire Asian region, by enrolling more patients in clinical trials, thus speeding up the process of developing new drugs.

Sep 9th, 2020 Press Release

https://www.ncc.go.jp/jp/information/pr_release/2020/0909/index.html



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Contact

- MASTER KEY Project Registry / clinical trials

Department of International Clinical Development,

National Cancer Center Hospital, Tokyo

Hitomi OKUMA

5-1-1 Tsukiji, Chuo-ku, Tokyo 104-0045

E-mail : NCCH2007_office@ml.res.ncc.go.jp

- **Others**

Office of Public Relations, Strategic Planning Bureau

E-mail : ncc-admin@ncc.go.jp